ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPTS-42031C; FRL-3212-4]

Biphenyl; Test Standards and Reporting Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule announces EPA's adoption of the study plans and schedule submitted by the Biphenyl Work Group for the testing of biphenyl (CAS No. 92-52-4). The tests for environmental effects and chemical fate, consisting of chronic testing on *Daphnia magna*, early life stage testing on rainbow trout, oyster toxicity, oyster bioconcentration, and aerobic and anaerobic biodegradation are required of manufacturers and processors of biphenyl under section 4(a) of the Toxic Substances Control Act (TSCA).

DATES: In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern ["daylight" or "standard" as appropriate] time on June 17, 1987. This rule shall become effective on July 17, 1987.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm., E-543, 401 M St., SW., Washington, DC 20460, (202) 554-1404.

SUPPLEMENTARY INFORMATION: EPA is issuing a final rule under section 4(a) of TSCA to require specific test standards and reporting deadlines be used in testing biphenyl.

I. Introduction

Test Rule Development Under TSCA

This notice is in implementation of section 4 of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*) which contains authority for EPA to require the development of data relevant to assessing the risk to health and the environment posed by exposure to particular chemical substances or mixtures.

Biphenyl (CAS No. 92-52-4) was designated by the Interagency Testing Committee (ITC) for priority testing consideration (47 FR 22585; May 25, 1982). EPA issued a proposed rule, published in the Federal Register of May 23, 1983 (48 FR 23080) in response to the testing recommendations by the ITC on biphenyl. EPA issued, under two-phase rulemaking, a final Phase I rule requiring testing of biphenyl published in the Federal Register of September 12, 1985 (50 FR 37182). For a detailed discussion of EPA's findings and testing requirements for all tests, refer to the final Phase I rule. In accordance with the Test Rule Development and Exemption Procedures for two-phase rulemaking in 40 CFR Part 790, persons subject to this rule were required to submit letters of intent to perform the testing or exemption applications. Those submitting letters of intent were required to submit proposed study plans and schedules for the testing required in the final Phase I rule.

On December 19, 1985, the Biphenyl Ad Hoc Group, now the Biphenyl Work Group (BWG), under the auspices of the Synthetic Organic Chemical Manufacturers Association, Inc. (SOCMA), notified EPA of certain companies' intent to sponsor the testing required in the final Phase I test rule and submitted proposed study plans and schedules for all required testing. The BWG includes Monsanto Co., Dow Chemical Co., Cheveron, Chemol, Coastal States Marketing, Koch Chemical, and Sybron Chemical Co.

After review and evaluation of these study plans, the Agency requested on January 3, 1986, that the BWG make certain revisions. On January 24, 1986, the Agency received from the BWG a complete set of study plans for all of the testing required for biphenyl. These study plans either contained revisions in response to the Agency's request or justifications, contained in cover letters, as to why certain suggested revisions were not made.

After review of the study plans, the EPA concluded that certain revisions were still necessary to transform these plans into acceptable test standards for the testing required for biphenyl. These revisions were incorporated into a document entitled "Revision of Study Plans for Biphenyl" which, together with the attached submitted study plans, are referred to as the EPA-modified study plans for biphenyl (Ref. 1). On July 15, 1986, the Agency proposed that these study plans be the required test standards and time schedules for the testing of biphenyl and solicited public comments on this proposal (51 FR 25577). After review of public comments, EPA is now promulgating a final Phase II rule requiring the sponsors of each test to conduct this testing in accordance with the revised EPA-approved modified study plans for biphenyl (Ref. 2). These study plans also incorporate revisions in response to public comments. These study plans shall become the test standards and reporting requirements for this substance.

II. Proposed Test Standards

The BWG notified EPA of their members' intent to sponsor the testing required in the final Phase I rule for biphenyl in 40 FR 799.925. The BWG members have also submitted proposed study plans for the required testing, which, after evaluation, the EPA revised resulting in the EPA-modified study plans for biphenyl. The BWG members proposed to sponsor the following studies: Flow-Through Chronic Toxicity with *Daphnia magna* Straus and Embryo-Larval Toxicity Test with Rainbow Trout, *Salmo gairdneri* Richardson (Dow Chemcial Co.), Oyster Shell Deposition Bioassay and Range-Finding Study, and Flow-Through Oyster Bioconcentration Study (Chevron Chemical Co.), Partitioning Water/Sediment Study, Aerobic Biodegradation Study, and Anaerobic Biodegradation Study (Monsanto Co.). As proposed by Monsanto in its protocol submissions, the partitioning water/sediment study was a separate but integral part of the aerobic and anaerobic biodegradation

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testing for biphenyl. In order to avoid ambiguity in the comment and reporting for this testing, the partitioning water/sediment study was proposed separately in the proposed test rule.

The EPA-modified study plans for all of these tests are available for inspection in the public record for the rulemaking. The Agency is now adopting these plans, which have been further modified as a result of public comments on the proposed rule, as the test standards for conducting the testing of biphenyl required under 40 CFR 799.925. All of the testing conducted according to the revised EPA-approved modified study plans for biphenyl shall be conducted in accordance with EPA's TSCA Good Laboratory Practice Standards as set forth in 40 CFR Part 792.

III. Response to Public Comments

On August 29, 1986, EPA received from the BWG their comments on the proposed Phase II rule for biphenyl. A public meeting was held on October 30, 1986, to discuss certain aspects of the early life stage testing of rainbow trout required for biphenyl. These comments are available in the public record for this rulemaking. The major issues identified during the comment period are discussed in Unit III., A. through D.

A. Anaerobic Biodegradation Study

The BWG noted that because of the problem of high adsorption of biphenyl, a number of study plan modifications are necessary for the anaerobic biodegradation study. Specifically, BWG stated that rubber septa and core tubes with septum seal parts cannot be used and that modified test vessels and modifications to the analytical methodology are needed to overcome this problem. The Agency agrees with this comment and, thus, has incorporated the suggested changes as part of the final study plans for the test (Ref. 3).

B. Partitioning Study

The BWG noted that the ratio of undisturbed sediment to water was mistakenly given as 3:1 in the proposed test standard; this should instead be a requirement of undisturbed sediment to water of 1:3 in order to yield enough water for biphenyl analysis and also in keeping with EPA's guidelines. EPA agrees that the original ratio was a transcription error and that the 1:3 ratio shall be the test requirement.

C. Oyster Bioconcentration

There was some concern by the BWG over language in the preamble which could be inferred to mean that more than one dose level was required in the oyster bioconcentration study; inconsistent with the proposed study plan. This notice clarifies the fact that only one dose level is required for this test for biphenyl, as is standard practice.

D. Rainbow Trout Embryo-Larval Test

The BWG and the sponsor of the rainbow trout embryo-larval test, Dow Chemical Co. (Dow), had two major concerns with this test as presented in the proposal. Their concerns were based on EPA's requiring that the test be performed starting with "green" eggs (fish embryos less than 96 hours old). The BWG and Dow stated in their comments that starting the test with "green" eggs was unnecessary. They believed that satisfactory results could more easily be obtained by starting the test with "eyed" eggs (embryos about 14 days old). The BWG also believed that starting the test with "green" eggs frequently results in excessive (control) mortality, invalidating the test. Furthermore, the test protocol as given in the proposal was inappropriate as written, if the requirement for starting the test with "green" eggs was adhered to.

The Agency disagrees that starting the test with "eyed" eggs will necessarily yield results equivalent to those when the test is started with "green" eggs. While there is some suggestive evidence that this may be the case (Refs. 5 and 6), the current data are not conclusive on this issue. At the present time, the Agency believes that the embryo-larval test, which is an already shortened chronic test, should not be further shortened unless more data become available which would support that particular change in protocol. The Agency recognizes that the successful performance of the early life stage test is more difficult when "green" eggs are used. The Agency also agrees that the protocol for the early life stage test as originally given in the proposed rule is deficient, and that there are procedures, pointed out by Dow in its public comments, that can be used to help ensure a successful test. Dow's newly submitted early life stage protocol (Ref. 4), reflecting these additional procedures, was therefore incorporated into the required testing standard for biphenyl for this study.

IV. Final Phase II Test Rule

A. Test Standards

In response to EPA's final Phase I rule for biphenyl, the BWG submitted study plans to conduct the testing required in the rule. The Agency, upon its evaluation of these study plans, believed that certain modifications were necessary and proposed the study plans, with modifications, as the EPA-modified study plans for biphenyl (Ref. 1). As a result of public comment on the proposed Phase II rule, EPA believed that further revision to the study plan was necessary. In the case of the study plan "Anaerobic and Aerobic Biodegradation of Biphenyl in Natural Sediment/Water Systems" and the study plan "Biphenyl: Embryo-Larval Toxicity Test with Rainbow Trout, *Salmo gairdneri* Richardson", the test sponsors resubmitted study plans (Ref. 3 and 4). These two sets of study plans are substituted into the original EPA-modified study plans for biphenyl for their corresponding earlier submissions along with EPA's revisions under this final rulemaking. Therefore, the study plans together with the final EPA revisions, are referred to as the "revised EPA-approved modified study plans for biphenyl" and shall constitute the test standards and reporting requirements for biphenyl as required under 40 CFR 799.925 (Ref. 2). The Agency believes that the conduct of the required tests in accordance with the revised EPA-approved modified study plans for biphenyl will ensure that the resulting data are reliable and adequate.

B. Reporting Requirements

The Agency is requiring that all data developed under this rule be reported in accordance with the TSCA Good Laboratory Practice (GLP) standards (40 CFR Part 792).

The Agency is required by TSCA section 4(b)(1)(c) to specify the time periods during which persons subject to a test rule must submit test data. EPA is specifying the schedules contained in the revised EPA-approved modified study plans for biphenyl as the reporting requirements. The reporting requirements for the final reports are summarized in the following table.

REPORTING DEADLINES FOR BIPHENYL

Test	Reporting deadline for final report (weeks after the effective date of final phase II rule)
Chronic Daphnid Toxicity [1]	30
Rainbow Trout Early Life Stage [1]	[2] 72 [3] (30)
Oyster Shell Deposition	65
Oyster Bioconcentration	[2] 87 [3] (35)
Partitioning Water/Sediment	39
Aerobic Degradation	52

REPORTING DEADLINES FOR BIPHENYL—Continued

Test	Reporting deadline for final report (weeks after the effective date of final phase II rule)
Anaerobic Degradation	56

[1] The order of these two tests may be reversed.
[2] Figure includes the time period required for previous required testing.
[3] Figure in parenthesis indicates the time period allowed for completion of the test itself, not including the time periods for previous required testing.

In addition, for each required test, EPA is requiring that progress reports be submitted at 6-month intervals, beginning 6 months after the effective date of the final rule.

C. Conditional Exemptions Granted

The final rule for test rule development and exemption procedures (40 CFR Part 790) indicates that, when certain conditions are met, exemption applicants will be notified by certified mail or in the final Phase II test rule for a given substance that they have received conditional exemptions from test rule requirements. The exemptions granted are conditional because they will be given based on the assumption that the test sponsors will complete the required testing according to the test standards and reporting requirements established in the final Phase II test rule for the given substance. TSCA section 4(c)(4)(B) provides that if an exemption is granted prospectively (that is, on the basis that one or more persons are developing test data, rather than on the basis of prior test data submissions), the Agency must terminate the exemption if the test sponsors have not complied with the test rule.

Since sponsors have indicated to EPA by letter of intent (Ref. 1) their agreement to sponsor all of the tests required for biphenyl in the final Phase I test rule for this substance (50 FR 37182; September 12, 1985), and EPA is adopting test standards and reporting requirements in this final Phase II rule, the Agency is hereby granting conditional exemptions to all exemption applicants for all of the testing required for biphenyl in 40 CFR 799.925.

Furthermore, while EPA has not identified manufacturers of biphenyl as a byproduct, such persons are covered by the requirements of this test rule and must apply for exemption from these testing requirements as set forth in 40 CFR Part 790.

D. Judicial Review

The promulgation date for the final Phase I test rule for biphenyl was established as 1 p.m. eastern daylight time on September 26, 1985 (50 FR 37182; September 12, 1985). To EPA's knowledge, no petitions for judicial review of that Phase I final rule were filed. Any petition for judicial review of this Phase II test rule for biphenyl will be limited to a review of the test standards and reporting requirements for this substance which are established in this notice.

E. Other Provisions

TSCA section 4 findings, required testing, test substance specifications, persons required to test, enforcement provisions, and the economic analysis are presented in the final Phase I test rule for biphenyl (50 FR 37182; September 12, 1985).

V. Rulemaking

EPA has established a record for this rulemaking [docket number OPTS-42031C)]. This record includes basic information considered by the Agency in developing this rule and appropriate **Federal Register** notices.

This record currently includes the following information:

A. Supporting Documentation

(1) Final Phase I rule on biphenyl (50 FR 37182; September 12, 1985).

(2) Proposed Phase II rule on biphenyl (50 FR 25577; July 15, 1986).

(3) Contact reports of telephone conversations.

(4) Letters and memoranda related to this rulemaking.

(5) Public comment on the proposed Phase II rule on biphenyl.

(6) Transcript of public meeting of October 17, 1986 on the proposed Phase II rule on biphenyl.

B. References

(1) Synthetic Organic Chemical Manufacturers Assocation (SOCMA). Letter from Alan W. Rautio (and attached study plans and associated cover letter) to TSCA Public Information Office. (January 24, 1986). [And attached Confirmation of EPA's Receipt, Evaluation, and Revisions. (July 8, 1986).]

(2) Synthetic Organic Chemical Manufacturers Association (SOCMA). Letter from Alan W. Rautio (and attached study plans and associated cover letter) to TSCA Public Information Office. (January 24, 1986). [And attached Final EPA Revisions of Study Plans for Biphenyl. (March 31, 1987).]

(3) Synthetic Organic Chemical Manufacturers Association (SOCMA). Letter from Alan W. Rautio (and attached study plans and associated cover letter) to Mr. J. Shaffer. (January 15, 1987).

(4) Synthetic Organic Chemical Manufacturers Association (SOCMA). Letter from Alan W. Rautio (and attached study plans and associated cover letter) to Mr. J. Schaffer. (December 5, 1986).

(5) Eaton, J.G., J.M. McKim, and G.W. Holcombe. "Metal toxicity to embryos and larvae of seven freshwater fish species—I. Cadmium". *Bulletin of Environmental Contamination and Toxicology* 19:95–103. (1978).

(6) McKin, J.A. "Evaluation of tests with early life stages of fish for predicting long-term toxicity." *Journal of the Fisheries Research Board of Canada* 34(8):1148–1154. (1977).

The record is available for inspection from 8 a.m. to 4 p.m. Monday through Friday except legal holidays, in Rm. G-004, Northeast Mall, 401 M Street, SW., Washington, DC 20460.

VI. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. This test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. The economic analysis of the testing of biphenyl is discussed in the Phase I test rule (50 FR 37182; September 12, 1985).

This final Phase II test rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments received from OMB, together with any EPA response to these comments, are included in the public record for this rulemaking.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.*, Pub. L. 96-354, September 19, 1980), EPA is certifying that this test rule will not have a significant impact on a substantial number of small businesses for the following reasons:

(1) There is not a significant number of small businesses manufacturing biphenyl.

(2) Small manufacturers and small processors of bipehnyl are not expected to perform testing themselves, or to participate in the organization of the testing effort.

(3) Small manufacturers and small processors of biphenyl should experience no costs, as they have been granted conditional exemption from the testing requirements of this rule.

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(4) Small manufacturers and small processors are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control number 2070–0033. No public comments on these requirements contained in the proposed Phase II rule for biphenyl (51 FR 25577; July 15, 1986) were submitted to the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 40 CFR Part 799

Testing, Environmental protection, Hazardous substances, Chemicals, Reporting and recordkeeping requirements.

Dated: May 22, 1987.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR Part 799 is amended as follows:

PART 799—[AMENDED]

1. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. By amending § 799.925 by revising paragraphs (c)(1)(ii), (2)(ii), (3)(ii) and (4)(ii) and (d)(1)(ii) and (2)(ii); adding paragraphs (c)(1)(iii), (2)(iii), (3)(iii), (4)(iii), and (d)(1)(iii), and (2)(iii), (d)(3), and (e) to read as follows:

§ 799.925 Biphenyl

* * * * *

(c) * * *

(1) * * *

(ii) *Test standard.* The test shall be conducted in accordance with the revised EPA-approved modified study plan submitted to EPA by the Biphenyl Work Group: "Embryo-Larval Toxicity Test with Rainbow Trout, *Salmo gairdneri* Richardson". This revised EPA-approved modified study plan is available for inspection in EPA's OPTS Reading Room, Rm. NE–G004, 401 M Street, SW., Washington. DC 20460; copies of this study plan are available for distribution to the public in the OPTS Reading Room.

(iii) *Reporting requirements.* The embryo-larval toxicity test of biphenyl with rainbow trout shall be completed and a final report submitted to the Agency within 72 weeks of the effective date of the final Phase II rule. However, if this study is performed before the flow-through chronic toxicity test with *Daphnia magna* described in paragraph (c)(2) of this section, then the final report for this rainbow trout early-life-stage shall be completed and a final report submitted to the Agency within 42 weeks from the effective date of the final Phase II rule. Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final Phase II rule.

(2) * * *

(ii) *Test standard.* The testing shall be conducted in accordance with the revised EPA-approved modified study plan submitted to EPA by the Biphenyl Work Group: "Flow-Through Chronic Toxicity Test with *Daphnia magna* Straus." This revised EPA-approved modified study plan is available for inspection in EPA's OPTS Reading Room, Rm. NE–G004, 401 M Street, SW., Washington, DC 20460; copies of this study plan are available for distribution to the public in the OPTS Reading Room.

(iii) *Reporting requirements.* The flow-through chronic toxicity test of biphenyl with *Daphnia magna* shall be completed and a final report submitted to the Agency within 30 weeks from the effective date of the final Phase II rule. However, if the embryo-larval toxicity test with rainbow trout described in paragraph (c)(1) of this section is performed before this study, then the final report for this chronic *Daphnia magna* study shall be completed and a final report submitted to the Agency within 72 weeks from the effective date of the final Phase II rule. Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final Phase II rule.

(3) * * *

(ii) *Test standard.* The testing shall be conducted in accordance with the revised EPA-approved modified study plan submitted to EPA by the Biphenyl Work Group: "Oyster Shell Deposition Bioassay and Range-finding Study". This revised EPA-approved modified study plan is available for inspection in EPA's OPTS Reading Room, Rm. NE–G004, 401 M Street, SW., Washington, DC 20460; copies of this study plan are available for distribution to the public in the OPTS Reading Room.

(iii) *Reporting requirements.* The oyster shell deposition and range-finding study with biphenyl shall be completed and a final report submitted to the Agency within 65 weeks from the effective date of the final Phase II rule. Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final Phase II rule.

(4) * * *

(ii) *Test standard.* The testing shall be conducted in accordance with the revised EPA-approved modified study plan submitted to EPA by the Biphenyl Work Group: "Flow-Through Oyster Bioconcentration Study". This revised EPA-approved modified study plan is available for inspection in EPA's OPTS Reading Room, Rm. NE–G004, 401 M Street, SW., Washington, DC 20460; copies of this study plan are available for distribution to the public in the OPTS Reading Room.

(iii) *Reporting requirements.* The oyster bioconcentration study shall be completed and a final report submitted to the Agency within 87 weeks from the effective date of the final Phase II rule. Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final Phase II rule.

(d) * * *

(1) * * *

(ii) *Test standard.* The testing shall be conducted in accordance with the revised EPA-approved modified study plan submitted to EPA by the Biphenyl Work Group: "Aerobic Biodegradation Study". This revised EPA-approved modified study plan is available for inspection in EPA's OPTS Reading Room, Rm. NE–G004, 401 M Street, SW., Washington, DC 20460; copies of this study plan are available for distribution to the public in the OPTS Reading Room.

(iii) *Reporting requirements.* The aerobic biodegradation study with biphenyl shall be completed and a final report submitted to the Agency within 52 weeks of the effective date of the final Phase II rule. Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final Phase II rule.

(2) * * *

(ii) *Test standard.* The testing shall be conducted in accordance with the revised EPA-modified study plan submitted to EPA by the Biphenyl Work Group: "Anaerobic Biodegradation Study". This revised EPA-approved modified study plan is available for inspection in EPA's OPTS Reading Room, Rm. NE–G004, 401 M Street, SW., Washington, DC 20460; copies of this study plan are available for distribution to the public in the OPTS Reading Room.

(iii) *Reporting requirements.* The anaerobic biodegradation study with biphenyl shall be completed and a final report submitted to the agency within 56 weeks of the effective date of the final Phase II rule. Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final Phase II rule.

(3) *Partitioning water/sediment study*—(i) *Required testing.* Testing using systems that control for and

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quantify biphenyl evaporation that use a ratio of undisturbed sediment to water of 1:3 shall be conducted with biphenyl to develop data on the partitioning of biphenyl to water and sediment.

(ii) *Test standard.* The testing shall be conducted in accordance with the revised EPA-approved modified study plan submitted to EPA by the Biphenyl Work Group: "Partitioning Water/Sediment Study". This revised EPA-approved modified study plan is available for inspection in EPA's OPTS Reading Room, Rm. NE-G004, 401 M Street, SW., Washington, DC 20460; copies of this study plan are available for distribution to the public in the OPTS Reading Room.

(iii) *Reporting requirements.* The partitioning water/sediment testing shall be completed and a final report submitted to the Agency within 39 weeks from the effective date of the final Phase II rule. Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final Phase II rule.

(e) *Effective date.* The effective date of the final Phase II rule for biphenyl is July 17, 1987.

[FR Doc. 87-12563 Filed 6-2-87; 8:45 am]
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